

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:

40277

CHEMISTRY REVIEW(S)

ANDA APPROVAL SUMMARY

ANDA: 40-277

DRUG PRODUCT: Proparacaine Hydrochloride Ophthalmic Solution

FIRM: Taylor Pharmaceuticals

DOSAGE FORM: Ophthalmic Solution **STRENGTH:** 0.5%

CGMP: Statement/EIR Update Status:

The EER is acceptable (OC recommendation, 1/11/00).

BIO: A waiver for bioequivalence study was granted by the Division of Bioequivalency, Office of Generic Drugs (1/7/98, James Chaney).

VALIDATION - (DESCRIPTION OF DOSAGE FORM SAME AS FIRM'S):

The drug substance and the drug product are included in the USP monographs. Method validation is not required.

STABILITY: (Are containers used in study identical to those in container section?)

The containers used in the stability study are identical to those described in the container section.

LABELING:

Container, carton and insert labeling have been found satisfactory (Labeling approval summary 4/22/99, reviewed by L. Golson)

STERILIZATION VALIDATION (IF APPLICABLE):

Sterilization and validation are evaluated to be satisfactory by the microbiological team (12/20/99).

SIZE OF BIO BATCH (FIRM'S SOURCE OF NDS OK?):

The liters of the exhibit batch of the Proparacaine Hydrochloride Ophthalmic Solution 0.5%, (lot#21206) were manufactured.

DMF (Proparacaine HCl USP drug substance) was found adequate (2/24/00, reviewed by Liang-Lii Huang, Ph.D.)

SIZE OF STABILITY BATCHES- (IF DIFFERENT FROM BIO BATCH, WERE THEY MANUFACTURED VIA THE SAME PROCESS?):

The exhibit batch (lot#21206) was the stability batch.

PROPOSED PRODUCTION BATCH - MANUFACTURING PROCESS THE SAME?:

The proposed production batches are liters for the Proparacaine Hydrochloride Ophthalmic Solution 0.5%. The manufacturing process will be the same as was used for the exhibit batch.

CHEMIST: Liang-Lii Huang, Ph.D.

DATE: February 24, 2000

SUPERVISOR: Paul Schwartz, Ph.D.

DATE: February 24, 2000

PS 2/24/00

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1. CHEMISTRY REVIEW NO. 6 (six)
2. ANDA # 40-277
3. NAME AND ADDRESS OF APPLICANT
Taylor Pharmaceuticals
Attention: James G. Baumann, Jr.
1222 West Grand Avenue
Decatur, IL 62525
4. LEGAL BASIS FOR SUBMISSION
The reference listed drug is Ophthaine® (Proparacaine Hydrochloride Ophthalmic Solution USP, 0.5%) manufactured by Apoteco. Ophthaine® is not covered by any patents or exclusivity provisions.
5. SUPPLEMENT(s)
None
6. PROPRIETARY NAME
None
7. NONPROPRIETARY NAME
Proparacaine Hydrochloride Ophthalmic Solution
8. SUPPLEMENT(s) PROVIDE(s) FOR:
N/A
9. AMENDMENTS AND OTHER DATES:
Date of submission - September 11, 1997
Major amendment - March 16, 1998
Major amendment - November 20, 1998
Facsimile amendment- May 20, 1999
Facsimile amendment- June 23, 1999
Amendment- September 7, 1999 (microbiology)
Amendment- November 19, 1999 (microbiology)
Minor amendment- February 7, 2000
10. PHARMACOLOGICAL CATEGORY
Topical anesthesia
11. Rx or OTC
Rx
12. RELATED IND/NDA/DMF(s)

Reference listed drug: Ophthaine® (Proparacaine Hydrochloride Ophthalmic Solution, USP, 0.5%)
NDA 08-883, approved in July 1, 1953
NDA holder: Apoteco (a Bristol-Myers Squibb company)

<u>DMF#(type)Product</u>	<u>DMF holder</u>	<u>LOA</u>
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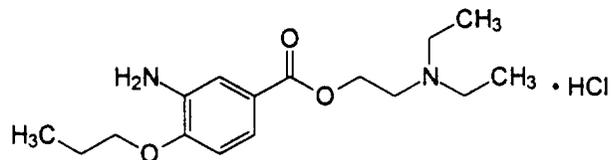
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13. DOSAGE FORM
Ophthalmic Solution

14. POTENCY
0.5%

15. CHEMICAL NAME AND STRUCTURE

Proparacaine Hydrochloride. Benzoic acid, 3-amino-4-propoxy, 2-(diethylamino)ethyl ester, monohydrochloride. $C_{16}H_{26}N_2O_3 \cdot HCl$. 330.86. 5875-06-9. Anesthetic (topical ophthalmic). USP 23, page 1315.



16. RECORDS AND REPORTS
N/A

17. COMMENTS
This application is approvable.

18. CONCLUSIONS AND RECOMMENDATIONS
This application is approvable.

19. REVIEWER: Liang-Lii Huang, Ph.D. DATE COMPLETED: February 24, 2000

Endorsed by Paul Schwartz, Ph.D./ February 24, 2000

cc: ANDA #40-277

ANDA #40-277/Division File

Field Copy

Endorsements:

HFD-627/Liang-Lii Huang, Ph.D./2/24/2000

HFD-627/P.Schwartz, Ph.D./2/24/2000

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Date: February 24, 2000

IS/ 2/24/00

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